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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/511,445 02/22/00 GORDON-KAMM

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HM22/0521

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EXAMINER

COLLINS,C

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED:

05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/511,445	GORDON-KAMM ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 February 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

18) Interview Summary (PTO-413) Paper No(s) _____
 19) Notice of Informal Patent Application (PTO-152)
 20) Other: _____

DETAILED ACTION

Priority

1. A foreign priority is not claimed.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, is attached to the instant Office action.

Drawings

3. The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948.

Specification

4. The disclosure is objected to because of the following informalities: The description of the drawings does not include a description for each figure of the drawings. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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7. The claims are drawn to a method for increasing crop yield through increased endoreduplication, said method comprising introducing into a plant cell an isolated viral replicase polynucleotide. The specification teaches only that introduction of an isolated viral replicase polynucleotide derived from the vector pWI-11 into maize scutellar cells causes increased reduplication in nuclei isolated from the leaves of transgenic plants as compared to nuclei isolated from the leaves of wild-type plants (pages 21-24 *Examples 1 and 2*), and that expression of the isolated viral replicase polynucleotide could be regulated by the use of tissue specific, cell specific, or inducible promoters (page 24 *Example 3*). The specification does not teach whether an increase in endoreduplication brought about by the introduction of an isolated viral replicase polynucleotide into a plant cell will also bring about an increase in crop yield, such as a comparison of the yield of a transgenic crop exhibiting increased endoreduplication with the yield of the corresponding wild-type crop.

8. Guidance for making and using the claimed invention is necessary for enablement because it is not known whether or under what circumstances increased endoreduplication may be correlated with increased crop yield. Larkins et al. teach that the physiological significance of endoreduplication is poorly understood (Journal of Experimental Botany, February 2001, Vol. 52, No. 355, pages 183-192). Hypotheses for why endoreduplication occurs include to increase the availability of DNA templates and thus increase gene expression, to maintain an optimum ratio between cell number and nuclear size, and to provide nitrogen storage for the embryo (page 183 paragraph spanning columns 1 and 2).

9. Given the uncertainty of whether increasing endoreduplication will increase crop yield, the absence of guidance in the specification for increasing crop yield by increasing

endoreduplication, the lack of working examples, and given the breadth of the claims which encompass methods for increasing the yield of any crop through endoreduplication increased as a result of introducing into any plant cell any isolated viral replicase polynucleotide operably linked to any promoter capable of driving expression in a plant cell, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Regarding claim 1, the term "or" renders the claim indefinite because it is unclear whether the promoter is driving expression in the target cell, or driving expression in an isolated viral replicase polypeptide.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 1-2, 4-8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Gronenborn (US 6,133,505 October 17, 2000).

15. The claims are drawn to a method of introducing into a plant target cell an isolated plant geminivirus viral replicase polynucleotide operably linked to a promoter, wherein the plant is the dicot tomato.

16. Gronenborn teaches a method of introducing into a plant target cell an isolated plant geminivirus viral replicase polynucleotide operably linked to a promoter, wherein the plant is the dicot tomato (column 32, lines 48-67 through column 34 lines 1-63).

17. Accordingly, claims 1-2, 4-8, and 10-11 are anticipated by Gronenborn.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gronenborn (US 6,133,505 October 17, 2000) in view of Grafi et al. (Proc. Natl. Acad. Sci. USA, August 1996, Vol. 93, pages 8962-8967, Applicant's IDS)

20. The claims are drawn to a method of introducing into a cell an isolated viral replicase polynucleotide, said method resulting in increased endoreduplication.

21. Gronenborn teaches a method of introducing into a cell an isolated viral replicase polynucleotide (column 32, lines 48-67 through column 34 lines 1-63).

22. Gronenborn does not teach increased endoreduplication as a result of said method.

23. Grafi et al. teach that inactivation of the *Zea mays* retinoblastoma protein (ZmRb) is correlated with the commencement of endoreduplication in maize endosperm (paragraph

spanning pages 8963-8964 and page 8966 *Figure 4*), and that ZmRb specifically binds the Wheat dwarf Virus Rep A LxCxE motif protein in vitro and in vivo (Page 8963 column 2). Grafi et al. also teach that endoreduplication requires transition from the G1 to the S phase of the cell cycle(page 8966 column 1). In addition, Grafi et al. teach that other viral LxCxE motif proteins can inactivate other retinoblastoma proteins, and that such inactivation causes cells to transition from the G1 to the S phase of the cell cycle (page 8966 column 1).

24. It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to introduce a viral replicase polynucleotide into a cell as taught by Gronenborn, for the purpose of increasing endoreduplication, given the teachings of Grafi et al. that the viral LxCxE motif proteins encoded by such polynucleotides could inactivate retinoblastoma proteins and cause a transition from the G1 to the S phase of the cell cycle, thus increasing endoreduplication.

25. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

May 18, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

